

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12837



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F.D.A. Consumer Safety Officer.

3-11-98

Sirs,

IT is To my Knowledge and First hand experience That This ephadra-ma Huang is extremely addictive, especially To people who have preexisting conditions of addiction.

I was Told This product was harmless, it would help enhance my workouts by giving me energy.

This product is not an energy Food, it is a drug - a stimulant and dangerous. IT should be Labeled as such if not removed all together.

I Started using This product about early June 95, within a month or so I Tablet a day one hour before a Workout Turned into 5 daily - Then 8 daily, 10 daily, eventually 20-25 a day.

Sleep was becoming impossible, yet need For pills seemed To increase. I was constantly under extreme Tension, Snapping on people Verbally almost constantly, and coming seriously close To physically assaulting people, especially close Family members.

Eventually I was so Far gone, I Started using Cocaine again and committing crimes.

This drug is dangerous and something must be done!

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Please reply, at Least Let me Know That you received my complaint. Also. Are There any class action Law suits pending That my Testimony will be usefull in. Thank You

make 1 copy
Adverse Event Questionnaire

Complaint Number: _____

Investigator: _____

| Consumer Information | | |
|--|--|--|
| Date of Report: <u>3-10-98</u> MM/DD/YY | Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <hr/> <input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC | |
| Name: [REDACTED] | Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M | Age: <u>31</u> |
| Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input checked="" type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown | | |
| Information on Adverse Event | | |
| Date of Adverse Event: <u>aprx. 11-95</u> | Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>Home</u> | |
| Previous Adverse Effects to Product Type: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| <p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <i>EXtreme Tension, Stress, -Feelings OF Mania. Ragingly Snapping on Family members. -Led to cocaine relapse, disorderly conduct and crime.</i></p> <p>How long did the symptoms last? <i>Constantly while under use.</i></p> <p>Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.). <i>I Started out Taking 1 pill 1 hour before a workout. Within a month I was Taking pills all day Long, every few hours and a couple at a time</i></p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: <i>Ephedra - Ma Huang</i></p> <p>Did event abate after use of suspected product <u>"stopped"</u> or dose reduced: <input checked="" type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown</p> <p>Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable</p> <p>Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable</p> | | |
| Medical Information | | |
| Was a health care provider seen?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | | <div style="writing-mode: vertical-rl; transform: rotate(180deg);"> RECEIVED CLINICAL RESEARCH & REVIEW/CSN 115-452 98 MAR 24 AM 9:46 </div> |
| Give health care provider's name, address and telephone number: | | |
| Occupation of Health Care Provider: <input type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) | | |
| What medical tests were performed and what were the results? | | |
| What was the medical diagnosis? | | |
| What treatment(s) was given (e.g., drugs, other)? | | |
| <p>Were there any preexisting condition(s)/treatment(s)? <i>Cocaine addiction</i></p> <p>(If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/>Yes <input type="checkbox"/>No <i>Drug Treatment.</i></p> | | |

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Product Category

1. Adverse event attributed to:

☐ Medical Food (under medical supervision) ☐ Infant Formula

☒ **Dietary Supplement** (a vitamin, an essential mineral, a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids, extracts from animal glands; garlic extract, fish oils; oil of evening primrose; fibers such as psyllium and guar gum, compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin, and mixtures of these ingredients)

☐ Other (traditional food) _____

Other Product Problems

2. ☐ Foreign Object (specify): _____

3. ☒ Other (specify): Being That Product is addictive - it Leads To possible relapse on other addictions.

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

(Ephadra-ma Huang)

NutraCeutical Corp

Solaray Inc. Clark City, Utah.

Diet Supp 1 To 2 daily
1 Tab cont. 375mg

Recomended To me as a workout enhancer by Health Food Store.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

Ephadra - ephedrine alkaloids. IT is To my know-
Ledge That This above product is an extremely pure
Form of ephedrine.

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐ Aspartame

☐ Color Additive (please specify) _____

☐ Monosodium Glutamate

☐ Sulfite

☒ Other ephedrine alkaloids

☐ Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐ Yes ☐ No ☒ Unknown Product

Sample Available: ☐ Yes ☐ No ☒ Unknown I may have a bottle at home, but do not have access to it right now.

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☐ No as I am a recovering addict from cocaine
addiction, and was a recovering addict at the
Life-Threatening: ☐ Yes ☐ No Time I consumed These pills, I firmly
Hospitalization: ☐ Yes ☐ No (if YES, indicate if initial or prolonged) believe These pills contri-
buted To my extreme
Required intervention to prevent permanent impairment/damage: ☐ Yes ☐ No Relapse of cocaine
abuse.
Did the adverse event result in a congenital anomaly: ☐ Yes ☐ No

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